



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

[Docket No. FDA-2013-N-0002]

New Animal Drugs; Dexmedetomidine; Lasalocid; Melengestrol; Monensin; and Tylosin;

Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Correcting amendments.

SUMMARY: The Food and Drug Administration (FDA) is correcting a document amending the animal drug regulations to reflect approval actions for new animal drug applications and abbreviated new animal drug applications during March 2013 that appeared in the Federal Register of April 30, 2013. FDA is correcting the approved strengths of dexmedetomidine hydrochloride injectable solution. This correction is being made to improve the accuracy of the animal drug regulations.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV-6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9019, [gghaibel@fda.hhs.gov](mailto:gghaibel@fda.hhs.gov).

SUPPLEMENTARY INFORMATION: The Food and Drug Administration (FDA) is correcting a document amending the animal drug regulations to reflect approval actions for new animal drug applications and abbreviated new animal drug applications during March 2013 that

appeared in the Federal Register of April 30, 2013 (78 FR 25182). FDA is correcting the approved strengths of dexmedetomidine hydrochloride injectable solution. This correction is being made to improve the accuracy of the animal drug regulations.

List of Subjects in 21 CFR Part 522

Animal drugs.

Therefore, 21 CFR part 522 is corrected by making the following correcting amendment.

PART 522--IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

2. In § 522.558, revise paragraph (a) to read as follows:

§ 522.558 Dexmedetomidine.

(a) Specifications. Each milliliter of solution contains 0.1 or 0.5 milligrams dexmedetomidine hydrochloride.

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Dated: May 31, 2013.

Bernadette Dunham,  
Director,  
Center for Veterinary Medicine.